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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,754	04/30/2002	Koji Yamauchi	SAEGU98.001APC	8824
20995	7590	02/12/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			YOON, TAE H	
			ART UNIT	PAPER NUMBER
			1714	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/019,754	Applicant(s) YAMAUCHI ET AL.	
	Examiner Tae H Yoon	Art Unit 1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "**the**" in "the elastic modulus" in line 2 of claim 5, for example, lacks an antecedent basis. It also applies to claims 6-12.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,514,291. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copolymer forming an artificial dura mater of said patent encompasses the instant amorphous and low crystalline polymer as evidenced by the same elastic modulus claimed in the instant claim 8.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taira et al (US 5,861,034).

Taira et al teach an artificial dura mater comprising a sheet made of bioabsorbable synthetic polymers formed from copolymers of lactic acid and  $\epsilon$ -caprolactone in abstract and examples. Said copolymers have a low modulus of elasticity as well as softness (col. 1, line 59-col. 2, line 3) which are inherent properties of an amorphous and low crystalline polymer. The use of a structural reinforcement is taught at col. 2, lines 19-28. The instantly recited physical properties are also inherent in an artificial dura mater of Taira et al since the same or similar polymer used in the instant invention is used.

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The reinforcement component such as polyglycolic acid of Taira et al also meets the instant Tg. Thus, the instant invention lacks novelty.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as obvious over Taira et al (US 5,861,034) and Williams et al (US 6,548,569).

Williams et al teach that polyglycolic acid (PGA) of Taira et al has a Tg of 35 °C in table 1, col. 37 which supports the examiner's position in above rejection.

Claims 1-16 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yamauchi et al (US 6,514,291).

Yamauchi et al teach the instant an artificial dura mater in examples and claims wherein the same or similar polymer used in the instant invention is used. Thus, the instant invention lacks novelty.

Claims 1, 2 and 5-9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams et al (US 6,548,569).

Williams et al teach various biodegradable amorphous and low crystalline polymer polymers having the instant physical properties (inherently) in table 1 and their use such as a dura mater (col. 19, line 64). Thus, the instant invention lacks novelty.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as obvious over Taira et al (US 5,861,034) or Yamauchi et al (US 6,514,291) in view of Rosen et al (US 4,364,126).

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The instant invention further recites a non-biodegradable structural reinforcement over Taira et al and Yamauchi et al. However, the use of a non-biodegradable polymer such as polypropylene or polyethylene in medical fields is well known as taught by Rosen et al, col. 3, lines 14-22.

It would have been obvious to one skilled in the art at the time of invention to utilize a non-biodegradable polymer such as polypropylene or polyethylene taught by Rosen et al in Taira et al or Yamauchi et al as a structural reinforcement since Taira et al and Yamauchi et al teach the use of a structural reinforcement and thus the use of the art well known non-biodegradable structural reinforcement would be a routine practice.

Claims 1-16 and 19 are rejected under 35 U.S.C. 103(a) as obvious over Rosen et al (US 4,364,126) in view of Taira et al (US 5,861,034) or Yamauchi et al (US 6,514,291).

Rosen et al teach the use of a non-biodegradable amorphous and low crystalline polymer such as polyvinylchloride or polypropylene (since it is soft and flexible) with a dura meter layered at col. 3, lines 14-22.

The instant invention further recites a biodegradable structural reinforcement over Rosen et al. However, Taira et al and Yamauchi et al teach a dura meter layered with a biodegradable structural reinforcement such as polyglycolic acid yarn in examples.

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It would have been obvious to one skilled in the art at the time of invention to utilize a biodegradable structural reinforcement such as polyglycolic acid yarn of Taira et al and Yamauchi et al in Rosen et al as a dura meter in combination with a non-biodegradable amorphous and low crystalline polymer such as polyvinylchloride or polypropylene since Rosen et al teach the use of a non-biodegradable amorphous and low crystalline polymer such as polyvinylchloride or polypropylene since Taira et al and Yamauchi et al teach the use of a biodegradable structural reinforcement and since the use of a biodegradable and non-biodegradable amorphous and low crystalline polymer in medical fields is a routine practice.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as obvious over Williams et al (US 6,548,569) in view of Taira et al (US 5,861,034) or Yamauchi et al (US 6,514,291) and Rosen et al (US 4,364,126).

The instant invention further recites a structural reinforcement over Williams et al. However, Williams et al teach that the PHAs (biodegradable amorphous and low crystalline polymer) can be combined with other polymers in any form at col. 28, lines 42-53.

Taira et al, Yamauchi et al and Rosen et al are discussed above.

It would have been obvious to one skilled in the art at the time of invention to utilize a biodegradable structural reinforcement and non-biodegradable amorphous and low crystalline polymer or non-biodegradable amorphous and low crystalline polymer and a biodegradable structural reinforcement in making a dura meter taught by Williams


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et al with teaching of Taira et al, Yamauchi et al and Rosen et al since the use of a biodegradable and non-biodegradable amorphous and low crystalline polymer as a structural reinforcement or a non- structural reinforcement in medical fields is a routine practice and since it is considered a design choice.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H Yoon whose telephone number is (571) 272-1128. The examiner can normally be reached on Mon-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Tae H Yoon  
Primary Examiner  
Art Unit 1714

THY/February 5, 2004